Briefing Paper
Biotech MCAN J-15-31

PART I: BACKGROUND DATA

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Options Meeting Date: August 6, 2015
Dispo Meeting Date: August 6, 2015

A. Submitter: Danisco

B. Chemical Identity:

(1) *Saccharomyces cerevisiae* strain [redacted]
(a) Recipient Microorganism: *Saccharomyces cerevisiae* strain [redacted]
(b) Donor Microorganism:
(i) [redacted]
(ii) [redacted]

C. Production volume
i) Maximum PV (Year 3): [redacted]

D. Use: ethanol production

PART II: Recommendation and Rationale

Drop from further review.

There is low risk to human health and the environment associated with the production of and use of *Saccharomyces cerevisiae* strain [redacted] containing the intergeneric genes encoding [redacted] e. The recipient microorganism is not pathogenic to humans, other animals, or to plants. It has a long history of safe use and is ubiquitous in the environment. [redacted] are common in many microorganisms and do not pose human health or ecological concerns. The [redacted] fermented into ethanol. The genes are stably inserted into the chromosome which reduces the potential for horizontal gene transfer if the microorganisms were inadvertently released in the environment. There are no bacterial vector sequences remaining in the production microorganism. The production microorganism does not

contain any introduced antibiotic resistance marker genes. Thus, there is low risk to human health and the environment with the manufacture and use of this *Saccharomyces cerevisiae* strain [redacted]

PART III: Introduction

The Agency has received a Microbial Commercial Activity Notice (MCAN) from Danisco US, Inc. (operating as DuPont Industrial Biosciences) for an intergeneric *Saccharomyces cerevisiae* strain that has [redacted]. In a previous submission ([redacted]) the recipient *S. cerevisiae* strain was modified by the introduction of a [redacted]. In the current submission, a [redacted] resulting in the new submission strain [redacted] The parental strain is *S. cerevisiae* [redacted] The genetic modifications allows for the [redacted] that can then be fermented into ethanol by the microorganism. The production microorganism, strain [redacted], will thus be used for production of fuel ethanol from grain.

Although *S. cerevisiae* is one of the ten microorganisms eligible for the 5(h)4 Tiered Exemptions from MCAN reporting, the company has chosen to submit this strain for an MCAN review [redacted]

PART IV: Hazard Summary

A. Human Health Hazard

The concern for human health effects associated with the recipient microorganism is low (Ward, 2015). The recipient strain for the MCAN submission is *Saccharomyces cerevisiae* which has extensive history of safe use. *Saccharomyces cerevisiae* is non-pathogenic and non-toxic.

The introduced genetic material also does not present health-related concerns. The production strain contains [redacted] Since the company uses personal protective equipment (lab coats, safety glasses, latex or nitrile gloves, uniforms, and respirators) during manufacturer, there is low concern for exposure and allergy due to the submission microorganism.

Since there are no introduced antibiotic resistance markers in the final organism, there is low concern for antibiotic resistance genes spreading in the environment.

B. Ecological Hazards

There are low ecological hazard concerns for the recipient microorganism, *S. cerevisiae* (Muneer, 2015). The recipient microorganism does not pose any pathogenicity/toxicity concerns to plants or animals. It is a benign yeast that is ubiquitous in the environment. The risk assessment of *S. cerevisiae* for the 5(h)4 Tiered Exemption stated that there are low ecological hazards associated with this microorganism.

The introduced [redacted] genes do not pose any concerns for pathogenicity/toxicity of the submission microorganism. [redacted] enabling its use on grains in ethanol production. Although the strain may survive if inadvertently released into the environment, there would be no ecological concerns (Muneer, 2015).